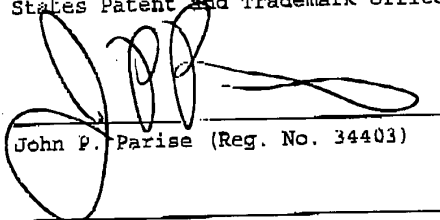


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I hereby certify that this correspondence is being facsimile transmitted to the United States Patent and Trademark Office, (Fax No. (703) 308-4242), on the date shown below.

  
John P. Parise (Reg. No. 34403)

August 22, 1996

Date

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application

Brockhaus, et al.

Group: 1806

Serial No. 08/444,791 filed May 19, 1995

Examiner: D. Adams

For: **HUMAN TNF RECEPTOR**

**REQUEST BY APPLICANTS**  
**FOR INTERFERENCE WITH PATENT**

Nutley, New Jersey 07110  
August 22, 1996

Assistant Commissioner for Patents  
Washington, D.C. 20231

Sir:

Pursuant to 37 C.F.R. §1.607 and 37 C.F.R. §1.608, applicants request that an interference be declared between the above-identified patent application and U.S. Patent No. 5,447,851, issued September 5, 1995 to Beutler, et al. ("Beutler Patent", copy enclosed).

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The subject patent application and the Beutler Patent claim the same patentable invention, and applicants propose the following count for an interference:

Proposed Count

A DNA segment having a sequence encoding a chimeric polypeptide comprising the extracellular domain of a TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide.

The proposed count is directed to a DNA segment and corresponds exactly to claim 66 of the subject application. The proposed count corresponds substantially to claim 1 of the Beutler Patent, except that the Beutler Patent claims the DNA segment as an isolated DNA segment. The term "isolated" lends no patentability to the claimed invention since the claimed DNA sequence is not found in nature. Thus, it is irrelevant to patentability whether the DNA sequence is isolated or not.

Proposed Count Covers Common Subject Matter

The Rule, 37 C.F.R. §1.601 and MPEP 2306, requires for declaring an interference between an application and an issued U.S. Patent and presenting a count that the claim of the application be drawn to the "same patentable invention" as the claim of the patent and that the count defines this "same patentable invention". In determining whether these claims define "the

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same patentable invention", the test set forth in 37 C.F.R. §1.601(f) and (n) is whether the subject matter claimed in the application is the same as (35 U.S.C. §102) or is obvious (35 U.S.C. §103) in view of the subject matter in the patent claim. It is clear that both claim 66 of the subject application and claim 1 of the Beutler Patent cover "the same patentable invention." The omission of the term "isolated" in defining the DNA segment does not render claim 1 of the Beutler Patent unobvious over claim 66 of the subject application.

The subject matter presented for interference relates to a DNA sequence encoding a chimeric polypeptide having the extracellular domain of a TNF receptor polypeptide functionally attached to the Fc portion and hinge region of an IgG heavy chain polypeptide. The issue of whether this DNA segment is isolated or incorporated into a vector does not make these DNA segments patentable over each other. In the Beutler patent, the segment is isolated and put into a vector. On the other hand, Example 11 of the subject application provides a different procedure where the DNA encoding extracellular domain of the TNF receptor is ligated into a vector which contains DNA encoding the Fc portion and hinge region of an IgG heavy chain polypeptide. In this manner, the segment containing the DNA of the count is not isolated but is formed as part of the expression vector. Therefore, it makes little difference whether the total DNA segment is isolated first and then put into a vector, or the DNA segment of the TNF receptor is placed into the vector containing the Fc portion and hinge region of an IgG polypeptide chain so that the

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DNA segment of the count is formed in the expression vector. Both constitute the same common invention.

Under 37 C.F.R. §1.601, the count should define the broadest same common invention claimed in the various interfering parties' applications. This is what the above proposed count does. By eliminating the term "isolated", the count covers the broadest common invention recited by claim 66 of the subject application and claim 1 of the Beutler Patent. In addition, the proposed count as formulated is in accordance with 37 C.F.R. §1.601, and conforms with the provisions of 37 C.F.R. §1.606 which require that:

"...a count shall not be narrower in scope than any application claim that is patentable over the prior art and designated to correspond to the count or any patent claim designated to correspond to the count."

Therefore, the proposed count conforms to 37 C.F.R. §1.606.

#### Parties, Application, and Patent

The parties and the patent and application in question are as follows:

Brockhaus, et al., Application No. 08/444,791, filed May 19, 1995  
Real Party in Interest - Hoffmann-La Roche Inc.

Beutler, et al., Patent No. 5,447,851, issued September 5, 1995  
Real Party in Interest - Believed to be the University of Texas

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Designated Claims

The claims that correspond to the proposed count are as follows: claims 1-25 in the Beutler Patent, and claims 48-55, 59-61, and 66-67 in the subject application.

The Designated Claims Cover Common Subject Matter

All designated claims relate to the biotechnology associated with a DNA sequence encoding a chimeric polypeptide comprising the extracellular domain of a TNF receptor polypeptide functionally attached to a Fc portion and hinge region of an IgG heavy chain polypeptide. Such biotechnology includes the DNA sequence itself, vectors containing the DNA sequence, host cells incorporating the DNA sequence, and methods of using the DNA sequence to produce the encoded for polypeptide.

The claims in the present application are patentable. On August 22, 1996, the Patent Office indicated that claims directed to the chimeric polypeptide encoded for by the presently claimed DNA is patentable. Applicants maintain that if the coded for polypeptide is patentable, then the DNA that encodes for such a polypeptide is also patentable. Moreover, the Patent Office has determined that the claims of the Beutler Patent are patentable, and the claims in the Beutler Patent and the present application are drawn to the same invention. Therefore, the Patent Office has in effect already determined that the claims of the present invention are patentable.

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Specification Support for New Claim 66

Applicants' new claim 66 is fully supported by the specification for the reasons recited in the concurrently filed Amendment.

The Requirements of 35 U.S.C. §135(b) Have Been Met

Applicants have presented new claim 66 within one year of the issue date of the Beutler Patent in compliance with 35 U.S.C. §135(b).

Applicants are Senior Party in this Interference

Applicants' present application is a division under 37 C.F.R. §1.60 of U.S. Patent Application No. 08/095,640, filed July 21, 1993, which is a continuation under 37 C.F.R. §1.60 of U.S. Patent Application No. 07/580,013, filed September 10, 1990, and the benefit of the earlier filing date is accorded under 35 U.S.C. §120 (over one and one-half years before the Beutler Patent filing date). The Beutler Patent has a filing date of April 2, 1992, and does not claim the benefit to an earlier filing date under U.S.C. §120. Based upon the filing dates, party Brockhaus, et al. is entitled to a judgment relative to the patentee. Consequently, in any interference proceeding, party Brockhaus, et al. is entitled to be Senior Party.

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Pending Divisional Applications

As discussed with Examiner Adams on July 23, 1996 in connection with the parent application, applicants are providing the following listing of divisional applications that claim the benefit of the priority application's filing date under 35 U.S.C. §120:

- Application No. 08/444,797, filed May 19, 1995 is in Group 1806 - Examiner Adams. Claims 44-55 are currently pending. Claims 48-53 are directed to a recombinant protein encoded by a polynucleotide which comprises two DNA subsequences, one of said subsequences encoding a soluble fragment of an insoluble protein capable of binding human tumor necrosis factor, and the other of said subsequences encoding all of the domains of the constant region of the heavy chain of a human immunoglobulin other than the first domain of said constant region. Therefore, claims 48-53 are coextensive with the invention claimed in the subject application.
- Application No. 08/444,793, filed May 19, 1995 is in Group 1806 - Examiner Adams. Claims 44-61 are currently pending. Claims 48-55 and 59-61 require a polynucleotide which comprises two DNA subsequences, one of said subsequences encoding an insoluble protein which has an apparent molecular weight of about 75 kilodaltons on a nonreducing SDS-polyacrylamide gel or a soluble fragment thereof which protein of fragment is capable of binding human tumor necrosis factor, and the other of said subsequences encoding all of the domains of the constant region of the heavy chain of a human immunoglobulin other than the first domain of said constant region. Therefore, claims 48-55 and 59-61 are coextensive with the invention claimed in the subject application.
- Application No. 08/444,790, filed May 19, 1995 is in Group 1806 - Examiner Nisbet. Claims 44-48 and 50-55 are currently pending. Claims 48 and 50-53 are directed to a recombinant protein encoded by a polynucleotide which comprises two DNA subsequences, one of said subsequences encoding a soluble fragment of an insoluble protein capable of binding tumor necrosis factor and having an apparent molecular weight of about 55 kilodaltons on a nonreducing SDS-polyacrylamide gel, which soluble fragment is capable of binding human tumor necrosis factor, and the other of said subsequences encoding all of the domains of the constant region of the heavy chain of a human immunoglobulin other than the first domain of said constant region. Therefore, claims 48 and 50-53 are coextensive with the invention claimed in the subject application.
- Application No. 08/095,460, filed May 19, 1995 is in Group 1806 - Examiner Adams. Claims 102-107 are currently pending have been found to be allowable by the Patent

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Office. These claims are directed to a recombinant protein encoded by a polynucleotide which comprises two DNA sequences, wherein the first subsequence encodes a soluble fragment of the insoluble TNF receptor protein, wherein said insoluble TNF receptor protein has a apparent molecular weight of about 55 kilodaltons as determined on a non-reducing SDS-polyacrylamide gel, and the second subsequence encodes all of the domains of the constant region of a human immunoglobulin heavy chain other than the first domain of said constant region.

In view of the above, applicants respectfully request that (1) an interference be declared between the subject application and the Beutler Patent, and (2) party Brockhaus, et al. be named Senior Party.

If any fee is required in connection with the filing of this Request, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 08-2525.

Respectfully submitted,

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/JPP  
Enclosure (1)  
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